



UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE

United States Patent and Trademark Office

Address: COMMISSIONER FOR PATENTS

P.O. Box 1450

Alexandria, Virginia 22313-1450

www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/507,343	09/10/2004	Hideo Ema	790086.405USPC	3862
500 7590 04/22/2008 SEED INTELLECTUAL PROPERTY LAW GROUP PLLC 701 FIFTH AVE SUITE 5400 SEATTLE, WA 98104				
EXAMINER SULLIVAN, DANIEL M				
ART UNIT		PAPER NUMBER		
1636				
MAIL DATE		DELIVERY MODE		
04/22/2008		PAPER		

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary

Application No.

10/507,343

Applicant(s)

EMA ET AL.

Examiner

Daniel M. Sullivan

Art Unit

1636

Period for Reply -- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 22 January 2008.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 5,8,12 and 87-90 is/are pending in the application.
- 4a) Of the above claim(s) 88-90 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 5,8,12 and 87 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO/S508)
Paper No(s)/Mail Date _____
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date _____
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: _____

DETAILED ACTION

This Office Action is a reply to the Paper filed 22 January 2008 in response to the Non-Final Office Action mailed 11 May 2007. Claims 13-86 were withdrawn from consideration and claims 1-12 were considered in the 11 May Office Action. Claims 1-4, 6, 7, 9-11 and 13-86 were cancelled, claims 5 and 8 were amended and claims 87-90 were added in the 22 January Paper. Claims 5, 8, 12 and 87-90 are pending.

Election/Restrictions

Newly submitted claims 88-90 are directed to an invention that is independent or distinct from the invention originally claimed for the following reasons: The claims are directed to a method of maintaining pluripotency of a stem cell without inducing differentiation comprising providing an isolated polypeptide having a WIF domain and an EGF-like repeat. Thus, the method is directed to a method of using the previously examined polypeptide. However, as established in the 11 May Office Action, the polypeptide used in the method now claimed was known in the art more than one year before the effective filing date of the instant application. Therefore, the technical feature that unites the previously examined invention with the newly presented claims is not a contribution over the art and is not a "special technical feature" as defined in PCT Rule 13.2.

Since applicant has received an action on the merits for the originally presented invention, this invention has been constructively elected by original presentation for prosecution on the merits. Accordingly, claims 88-90 withdrawn from consideration as being directed to a non-elected invention. See 37 CFR 1.142(b) and MPEP § 821.03.

Claims 5, 8, 12 and 87 are presently under consideration.

Response to Amendment and arguments

Claim Objections

Objection to claim 5 because the claim sets forth sequence data without providing a corresponding SEQ ID NO. is **withdrawn** in view of the claim amendments.

Claim Rejections - 35 USC § 101

35 U.S.C. 101 reads as follows:

Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

Rejection of claims 5, 8 and 12 under 35 U.S.C. 101 because the claimed invention is directed to non-statutory subject matter is **withdrawn** in view of the claim amendments.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 5, 8 and 12 **stand rejected** and newly presented claim 87 **is rejected** under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. This rejection was made in the

previous Office Action and is set forth herein below in modified form as necessitated by the claim amendments.

Vas-Cath Inc. v. Mahurkar, 19USPQ2d 1111, clearly states that “applicant must convey with reasonable clarity to those skilled in the art that, as of the filing date sought, he or she was in possession *of the invention*. The invention is, for purposes of the ‘written description’ inquiry, *whatever is now claimed*.” (See page 1117.) The specification does not “clearly allow persons of ordinary skill in the art to recognize that [he or she] invented what is claimed.” (See *Vas-Cath* at page 1116).

In the instant case, the claims are directed to a composition comprising an isolated polypeptide having a WIF domain and an EGF-like repeat and an isolated stem cell survival agent selected from SCF, Flt-3 ligand and TPO. The claim further recites that the polypeptide having a WIF domain encompasses a polypeptide comprising a WIF domain consists of at least 100 amino acids of the amino acid sequence set forth in SEQ ID NO: 4 and an amino acid sequence that is derived from a polypeptide consisting of SEQ ID NO: 4 or a polypeptide consisting of at least 100 amino acids of the amino acid sequence set forth in SEQ ID NO: 4, wherein the WIF domain polypeptide is capable of maintaining pluripotency of a stem cell without differentiating the stem cell.

With regard to scope, it is first noted that the polypeptide comprising SEQ ID NO: 4 is 379 amino acids long while the specification teaches that the amino acid positions 30 to 180 of the SEQ ID NO: 4 correspond to the WIF domain within that sequence. (See, e.g., the brief description of Figure 1.) As the claims do not require that the WIF domain fragment contain sequence from the 30-180 amino acid segment of SEQ ID NO: 4, a polypeptide having a WIF

domain comprising a WIF domain polypeptide consisting of at least 100 (or even 150) amino acids of the sequence set forth as SEQ ID NO: 4 might contain very little sequence from the region purported to be the WIF domain within SEQ ID NO: 4. For example, a polypeptide comprising amino acids 150 to 250 of SEQ ID NO: 4 is within the scope of the claims even though only 30 amino acids of that sequence are contained within the region identified as the WIF domain of SEQ ID NO:4. Likewise, a polypeptide comprising the sequence 1-100 of SEQ ID NO: 4 are within the claim scope even though more than half of the sequence identified as the WIF domain of SEQ ID NO: 4 is not present in the polypeptide. The claims also embrace polypeptides wherein any 10 amino acids of the SEQ ID NO: 4 sequence or the sequence comprising as few as 100 amino acids of the SEQ ID NO: 4 sequence can be deleted, added or substituted with any other amino acid and the WIF domain polypeptide is capable of maintaining pluripotency of a stem cell without differentiating the stem cell. Thus, the polypeptide of the claims embraces a broad and structurally divergent genus of molecules.

The written description requirement for a claimed genus may be satisfied through sufficient description of a representative number of species. A “representative number of species” means that the species which are adequately described are representative of the entire genus. Thus, when there is substantial variation within the genus, one must describe a sufficient variety of species to reflect the variation within the genus. The disclosure of only one species encompassed within a genus adequately describes a claim directed to that genus only if the disclosure “indicates that the patentee has invented species sufficient to constitute the gen[us].” See *Enzo Biochem*, 323 F.3d at 966, 63 USPQ2d at 1615.

In the instant case, the application discloses five species homologues of WIF-1 (see, e.g., Figure 1 and the caption thereto) and discloses WIF-1 polypeptides comprising conservative substitutions at 4 amino acid positions (two in the WIF domain; see especially Example 8, paragraph bridging pages 97-98). The specification demonstrates that the wild-type murine WIF-1 polypeptide is capable of enhancing proliferation of hematopoietic stem cells in the presence of stem cell factor (SCF). (See especially Example 4, Tables 2 and 3.) The specification also teaches that a WIF-1 protein comprising the four conservative substitutions within the sequence set forth as SEQ ID NO: 2 retained the capacity to enhance proliferation of hematopoietic stem cells in the presence SCF. However, given the broad scope of the structural variants within the scope of the claims, the few species of closely related polypeptides disclosed in the application fail to convey the necessary common attributes or features of the genus claimed.

The written description requirement for a claimed genus may be satisfied through disclosure of the relevant, identifying characteristics, i.e., structure or other physical and/or chemical properties, by functional characteristics coupled with a known or disclosed correlation between function and structure, or by a combination of such identifying characteristics, sufficient to show the applicant was in possession of the claimed genus. (See MPEP §2163(3)(a)(ii)).

In the instant case, the disclosure provides no specific guidance beyond the species explicitly disclosed that would convey the relevant identifying characteristics of a broadly divergent genus of polypeptides having the function of maintaining pluripotency without differentiating a stem cell. It is noted that the claims encompass any polypeptide comprising the generic “WIF domain” of the claims, but there is no disclosure of the fragments of the SEQ ID NO: 4 sequence the functional properties recited in the claims and, aside from the four

Art Unit: 1636

conservative substitutions reduced to practice, there is no disclosure of how the protein can be modified while retaining the recited function. In particular, there is no disclosure of which amino acids and amino acid sequences are critical to the recited function. Although the disclosure provides some generic teachings related to modifying polypeptide sequences (pp. 34-38), the art teaches that the effect of modifying amino acid sequence on the function of a polypeptide is highly unpredictable. For example, Richards (1997) Cell Mol. Life Sci. 53:790-802 teaches, “[i]n terms of structural alterations and thermostability, responses to genetic mutations are context dependent and remain difficult to predict with any confidence” (abstract, column 1). Thus, Richards teaches that the effect of mutation on protein stability, a prerequisite for biological function, is unpredictable. Richards also teaches that even limited amino acid modifications can have dramatic effects on protein structure and function. In the second column on page 791, Richards cites the example of influenza virus hemagglutinin protein, wherein alterations in the ionization state of just a few ionizable groups dramatically alters the biological behavior of the molecule. Citing a published study of done on the gene V protein, Richards teaches that, in spite of only limited modification at two amino acid positions, “[t]he effects on the overall stability of the protein were remarkably variable” (page 794, column 1). In the paragraph bridging pages 796 and 797, Richards teaches, “[i]n single site mutants, the structural changes are generally greatest near the site of mutation, and moving away, decrease radially in all directions. Even the small changes are so complex that the linkage relations do not allow assignments of the energetic changes to unique parts of the altered residue and its immediate contacts” (emphasis added) and “[t]here is no convincing explanation yet of how the changes in binding can produce a major movement over such a distance.” Finally, in the first full paragraph in the second column on page

793, Richards teaches, “[a]lmost all mutations are accompanied by some conformational change, making prediction of the effects on stability difficult. In most cases mutations lead to lowering of the stability.” (emphasis added). Thus, Richards teaches that small changes in the primary structure of a protein frequently have dramatic effects on the higher order structure and function of the protein, and that these effects are highly unpredictable.

Although the specification discloses methods by which one might identify compounds having the activities of the claimed compounds, an adequate written description of a compound requires more than a mere statement that it is part of the invention and reference to a potential method for isolating it; what is required is a description of the compound itself. It is not sufficient to define a compound solely by its principal biological property because disclosure of no more than that, as in the instant case, is simply a wish to know the identity of any compound with that biological property. Also, naming a type of material generically known to exist, in the absence of knowledge as to what that material consists of, is not a description of that material. Thus, claiming all polypeptides and agents that achieve a result without defining what means will do is not in compliance with the description requirement. Rather, it is an attempt to preempt the future before it has arrived. (See *Fiers v. Revel*, 25 USPQ2d 1601 (CA FC 1993) and *Regents of the Univ. Calif. v. Eli Lilly & Co.*, 43 USPQ2d 1398 (CA FC, 1997)).

Finally, it is noted that the claims recite “said WIF domain polypeptide is capable of maintaining pluripotency of a stem cell without differentiating the stem cell”. The antecedent of “said WIF domain polypeptide” must be “a WIF domain polypeptide” recited in parts (b), (c) and (d) of claim 8, which is defined as a fragment of the SEQ ID NO: 4 sequence, rather than “an isolated polypeptide having a WIF domain and an EGF-like repeat”, which is the claimed

polypeptide as a whole. Therefore, the function of "maintaining pluripotency of a stem cell without differentiating the stem cell" according to the claims is independent of the EGF-like repeat portion of the disclosed WIF-1 polypeptide. However, the instant application teaches that the ability of WIF-1 polypeptides to enhance proliferation of hematopoietic stem cells in the presence SCF is dependent upon both the WIF domain and the EGF-like repeat domain of the WIF-1 protein. (See especially page 101, paragraph 4.) Thus, the presence of even the amino acid sequence from about position 30 to about position 180 of the sequence set forth as SEQ ID NO: 4 does not reliably identify a protein as having the ability to enhance proliferation of hematopoietic stem cells in the presence SCF and one would not conclude that applicant was in possession of any fragment of SEQ ID NO: 4 having the recited activity independent of the EGF domain.

In view of these considerations, a skilled artisan would not have viewed the teachings of the specification as sufficient to show that the applicant was in possession of the claimed invention commensurate to its scope because it does not provide adequate written description for the broad class of claimed polypeptides and agents. Therefore, only the explicitly disclosed species meet the written description provision of 35 U.S.C. §112, first paragraph.

Response to Arguments

In response to the *prima facie* rejection of record, Applicant submits, with regard to an isolated WIF domain polypeptide, as disclosed in the specification and recited in the claims, that such polypeptides are supported by numerous references to, inter alia, a polypeptide comprising the amino acid sequence set forth in SEQ ID NO: 4, as set forth in original claim 10 and in the

Sequence Listing, and as described for use in the presently claimed embodiments in the specification. Applicant urges that the specification clearly conveys to the skilled person that at the time of filing applicants were in possession of a WIF domain polypeptide, in particular by teaching that a WIF domain refers to the N-terminal region of the WIF-1 protein without the signal peptide and extending to the start of the EGF-like repeat (citing, e.g., page 29, line 11 through page 30, line 9), and further by explaining that the WIF domain includes the amino acid sequences running from about position 30 to about position 180 in these SEQ ID NOs, beyond which the presence of an EGF-like repeat-containing domain can be recognized, as also clearly described.

Applicant further contends that the specification also clearly describes smaller WIF domain-containing polypeptides, such as those that include at least 100, 110, 120, 130, 140 or 150 amino acids of the amino acid sequence at about position 30 to about position 180 in SEQ ID NO:4 (citing, e.g., page 29, lines 1-4) and teaches how to confirm the function of such a WIF domain polypeptide using an *in vitro* Wnt protein inhibition assay according to art accepted methodology. Applicant particularly cites Example 8, which describes how similar conservatively substituted derivatives of SEQ ID NO: 2 were made and tested to show that the so-modified WIF domain polypeptide was capable of maintaining pluripotency of a stem cell without differentiating the stem cell.

This argument is not persuasive. The question with regard to written description is not whether the application contains statements that variants are viewed as within the scope of the invention, the question is whether the application clearly describes the variants having the required function such that one of skill in the art would recognize that applicant was actually in

possession of those variants at the time of filing. The fact that a statement of an invention is in an original claim does not necessarily end all inquiry as to the satisfaction of the written description requirement. See *Enzo Biochem Inc. v. Gen-Probe Inc.*, 63 USPQ2d 1609 (CA FC 2002) at 1616 (“[R]egardless whether the claim appears in the original specification and is thus supported by the specification as of the filing date, § 112, ¶ 1 is not necessarily met... If a purported description of an invention does not meet the requirements of the statute, the fact that it appears as an original claim or in the specification does not save it. A claim does not become more descriptive by its repetition, or its longevity.”). Furthermore, in *Enzo*, the Court rejected Enzo’s argument that the written description requirement for generic claims is necessarily met as a matter of law because the claim language appears in *ipsis verbis* in the specification, stating, “Even if a claim is supported by the specification, the language of the specification, to the extent possible, must describe the claimed invention so that one skilled in the art can recognize what is claimed. The appearance of mere indistinct words in a specification or a claim, even an original claim, does not necessarily satisfy that requirement” and “The disclosure must allow one skilled in the art to visualize or recognize the identity of the subject matter purportedly described” (*Id.* at 1616).

In addition, Applicant’s contention that one of skill in the art could empirically determine which variants have the recited activity and, therefore, are within the claim scope does not support compliance with the written description requirement of 35 USC § 112, first paragraph. See *Ex parte Kubin*, 83 USPQ2d 1410 (Bd. Pat. App. & Int. 2007) (“Possession may not be shown by merely describing how to obtain possession of members of the claimed genus or how to identify their common structural features.” (*Id.* at 1417; citing *University of Rochester*, 358

F.3d at 927, 69 USPQ2d at 1895); “Without a correlation between structure and function, the claim does little more than define the claimed invention by function. That is not sufficient to satisfy the written description requirement.” (*Id.* at 1417; citing *Eli Lilly*, 119 F.3d at 1568, 43 USPQ2d at 1406.)) With regard to Example 8, the example fails to evidence adequate written description for what is claimed because the claims are not limited to those species and the species disclosed, having highly conservative single amino acid substitutions of a single amino acid sequence, are not representative of the full scope of what is claimed and do not convey the relevant identifying characteristics of the genus of polypeptides embraced by the claims.

Applicant’s arguments have been fully considered but are not deemed persuasive in view of the record as a whole. Therefore, the claims stand rejected under 35 USC § 112, first paragraph, as lacking adequate written description.

Claim Rejections - 35 USC § 102

Rejection of claims 5 and 8 under 35 U.S.C. 102(b) as being anticipated by Hsieh et al. (1999) *Nature* 398:431-436 (made of record in the IDS filed 2 February 2005) is **withdrawn** in view of the amendment of the claim such that it is drawn to a composition comprising the WIF domain polypeptide and a stem cell survival agent selected from SCF, Flt-3 and TPO. Hsieh et al. does not teach the combination.

Claim Rejections - 35 USC § 103

Rejection of claim 11 is rejected under 35 U.S.C. 103(a) as being unpatentable over Hsieh et al. (*supra*) in view of Racher et al. (1995) *Biotechnol. Techniques* 9:169-174 is **withdrawn** in view of the amendment of the claim such that it is drawn to a composition

Art Unit: 1636

comprising the WIF domain polypeptide and a stem cell survival agent selected from SCF, Flt-3 and TPO. The art does not teach or suggest the combination.

New Grounds Necessitated by Amendment

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 5, 8, 12 and 87 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. This is a New Matter rejection.

The MPEP states, “[i]f new matter is added to the claims, the examiner should reject the claims under 35 U.S.C. §112, first paragraph-written description requirement. *In re Rasmussen*, 650 F.2d 1212, 211 USPQ 323 (CCPA 1981).” (MPEP §2163.06). The MPEP further states, “[w]henver the issue arises, the fundamental factual inquire is whether a claim defines an invention that is clearly conveyed to those skilled in the art at the time the application was filed. . . If a claim is amended to include subject matter, limitations, or terminology not present in the application as filed, involving a departure from, addition to, or deletion from the disclosure of the application as filed, the examiner should conclude that the claimed subject matter is not described in the application” (*Id.*, §2163.02). The introduction of claim changes which involve

narrowing the claims by introducing elements or limitations which are not supported by the as-filed disclosure is a violation of the written description requirement of 35 U.S.C. 112, first paragraph. See, e.g., *Fujikawa v. Wattanasin*, 93 F.3d 1559, 1571, 39 USPQ2d 1895, 1905 (Fed. Cir. 1996).

The amended claims define a WIF domain polypeptide consisting of a sequence of at least 100, etc. amino acids of the amino acid sequence set forth in SEQ ID NO: 4. The closest teaching in the original filed disclosure is found in the passage beginning at page 28, line 14, which states, “[A] shorter WIF domain will include, among the group of...the identical sequence of the amino acid number at about position 30 to at about position 180 of human WIF domain as set forth in SEQ ID NO: 4...at least 100 amino acids, [etc.]...of this group.” Thus, the passage defines a group of amino acids from about position 30 to about position 180 of SEQ ID NO: 4 and then contemplates fragments “of this group”. In contrast, the instant claims recite WIF domain fragments of the entire SEQ ID NO: 4 polypeptide, which defines a genus that is substantially different from a genus constrained to comprising fragments of the sequence from at about position 30 to at about position 180 of SEQ ID NO: 4 as contemplated in the original disclosure. In view of this, the claims as amended contain impermissible new matter.

Conclusion

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

Art Unit: 1636

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Daniel M. Sullivan whose telephone number is 571-272-0779. The examiner can normally be reached on Monday through Friday 6:30-3:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Joseph Weitach, Ph.D. can be reached on 571-272-0739. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Daniel M Sullivan/
Primary Examiner, Art Unit 1636